EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327 MDL 2327
	)	JOSEPH R. GOODWIN
	)	U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO WAVE 11 CASES	)	

- - -

Monday, August 12, 2019

- - -

DEPOSITION OF RICHARD M. WASSERMAN, M.D., held at Greenberg Traurig, 10845 Griffith Peak Drive, Suite 600, Las Vegas, Nevada, commencing at 9:31 a.m., on the above date, before Janet C. Trimmer, NV CCR 864.

- - -

GOLKOW LITIGATION SERVICES
phone 877.370.DEPS / fax 917-591-5672
deps@golkow.com

A P P E A R A N C E S

On behalf of the Plaintiffs:
WAGSTAFF & CARTMELL, LLP
BY: ANDREW N. FAES, ESQ.
4740 Grand Avenue
Suite 300
Kansas City, Missouri 64112
(818) 701-1100
afaes@wcllp.com

On behalf of the Defendants:
BOWMAN AND BROOKE LLP
BY: BARRY J. KOOPMANN, ESQ.
150 South Fifth Street
Suite 3000
Minneapolis, Minnesota 55402
(612) 339-8682
barry.koopmann@bowmanandbrooke.com

I N D E X

E X H I B I T S

EXHIBITS (CONTINUED)

INFORMATION REQUESTED

Page	Line
19	12
22	14

Las Vegas, Nevada; Monday, August 12, 2019

-oOo-

Whereupon --

(In an off-the-record discussion held prior to the commencement of the proceedings, counsel agreed to waive the court reporter's requirements under Rule 30(b)(5)(A) of the Federal Rules of Civil Procedure.)

RICHARD M. WASSERMAN, M.D.
having been first duly sworn to testify to the truth, was examined and testified as follows:

EXAMINATION

BY MR. FAES:

Q. Good morning, Dr. Wasserman. Could you state your full name for the record, please?

A. Richard Marc Wasserman.

Q. You have been hired as a general liability expert for Ethicon in this litigation; is that correct?

A. Yes.

Q. And you produced an expert report that's dated March 21st of 2019; right?

Page 26

A. I do. I think an expert opinion should be unbiased and objective, yes.
Q. Okay. And when you gave your opinions in this litigation, you wanted those opinions to be as accurate as possible; right?
A. Yes.
Q. You wanted to be as thorough in your review of the available information, documents, and literature as possible; right?
A. Yes.
Q. And you wanted to make sure that you got all of the information on the pertinent issues in the case before giving your opinions; right?
MR. KOOPMANN: Object to form.
THE WITNESS: Yes.
BY MR. FAES:
Q. Do you feel like you have all of the pertinent information that you need in order to issue your opinions in this case?
A. I feel as though the documents that I have reviewed are adequate for my being able to form an opinion on these four products.
Q. Is it fair to say that you want to get both sides of the story before issuing your opinions in this case?

Page 27

A. I don't really understand what you mean by "both sides of the story."
Q. Well, it's fair to say that you want to consider both information that supports your opinions that the TVT devices are safe and effective, and you want to look at any information that suggests that the devices are not safe and effective; right?
A. I look at all information, all the information that was provided, yes.
Q. Okay. And you would want to look at all of the information that supports that there might be a defect or problem with the TVT products as well as information that suggests that there isn't a defect or problem with the TVT devices; right?
A. Well, I would look at the quality information; correct. It's a question of all information versus quality information. I'm sure that there's information out there that is not high-quality information. So non-high-quality information is -- I don't think I would put much weight on that.
Q. Okay. What do you consider to be not-high-quality information? Do you have any examples of materials in this case that you reviewed that you considered to be not high quality?
A. There's a number of stuff that I've reviewed

Page 28

for this case. Some of it is high quality; some of it is not high quality. I don't have a list of what specific ones offhand.
Q. Okay. In general, are there any sources or items that you consider to be not high quality?
A. Generally, let's talk about high quality. High quality is like the level I type studies, the Cochrane databases, the meta-analysis, the statements from the societies. That, I would consider to be higher quality as opposed to non-level-I-type material.
Q. Okay. Do you consider testimony from Ethicon medical directors to be high-quality evidence?
A. Not really, no.
Q. And why is that?
A. Because it's just the opinion of one person, and as opposed to the opinion of a medical society or as opposed to a level I research article. A single opinion of one individual is one individual's opinion.
Q. So you consider the testimony of Ethicon's paid medical directors that they hire to be not high quality; is that accurate?
MR. KOOPMANN: Object to form.
THE WITNESS: I wouldn't place too much value on that as far as evidence, as far as material that I

Page 29

would use into forming an opinion.
BY MR. FAES:
Q. Okay. It's fair to say that the opinions of Ethicon's medical directors that Ethicon hired and selected to be responsible for the transvaginal mesh products, you don't consider their opinions to be high quality; correct?
MR. KOOPMANN: Object to form.
THE WITNESS: I don't think that the opinion of one person has much value when you look at the body of literature.
BY MR. FAES:
Q. Do you consider internal documents from Ethicon employees, such as engineers and people who actually worked on the design of the products, to be high quality?
A. Again, that's the opinion of one person. That's not the opinion of a medical society or a large data review. So I wouldn't -- I'd put that as the opinion of just one person.
Q. Okay. So it's fair to say that you don't consider the opinions of engineers who actually worked on the design of the TVT products to be high quality; correct?
A. Again, that's just the opinion of one

Page 30

specific individual. So when I review material for forming my opinion, I would not base it on one specific individual's conclusions.

Q. I understand that, but my question is a little different and more specific than that.

My question is, do you consider the opinions of engineers who actually worked on the design of the TVT products to be of high quality?

A. I think that it's not that high quality. I think it's just the opinion of one specific individual. I don't put too much weight or value on it. I've looked at those documents and I've kind of looked at them, going okay, that's that guy's opinion, or that one's opinion, and okay. But what does the body of literature say? And the body of literature differs from some of those internal documents that you are alluding to.

Q. Okay. What about the -- if it's a -- strike that.

What if we're talking about sworn testimony from an engineer, a person who worked on the design of the TVT products? Is your answer the same with regard to testimony as it is to documents?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, I would agree. I think

Page 31

they are just the opinion of one individual, so I don't put too much weight on that.

BY MR. FAES:

Q. Do you put any additional weight or consider it to be of higher quality if multiple engineers who worked on the design of the TVT product express the same viewpoint or opinion?

A. Again, it's multiple individuals' opinions.

Q. Do you put any additional weight -- well, I'm going to have to back up, because I'm not sure that exactly answers my question. I understand we're talking about individuals, but my question is a little different.

My question is, does your assessment of the quality of the evidence change if multiple engineers or persons who worked on the actual design of the TVT products expressed the same opinion?

A. Again, I don't put too much weight on those opinions.

Q. But does it change at all? Does it make it more or less credible if multiple persons express the same opinion?

A. It does not.

Q. Okay. If multiple medical directors for Ethicon and Johnson & Johnson who were responsible for

Page 32

overseeing the efficacy and safety of the transvaginal mesh products, including the TVT, expressed the same viewpoint, does that change your assessment in any way of the quality of that evidence?

A. It does not. So the evaluation of the TVT and all the products that we're talking about today, there's a body of literature out there that I place a high value on. Individual's specific opinions regarding the TVT and comments that they have made or anything that they've said as an individual, I don't place too much weight on.

Q. Okay. Would you agree that the primary responsibility of Ethicon's medical directors was to ensure the safety and efficacy of the TVT products?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: I do not know what the primary responsibility of Ethicon's medical director is. I can't speak to that.

BY MR. FAES:

Q. Okay. But you've reviewed testimony of some of Ethicon's medical directors; right?

A. I have.

Q. Do you recall reviewing the deposition of Richard Isenberg?

A. The name sounds familiar. I'm terrible with

Page 33

names. So the name sounds familiar, but I'm not sure exactly which one that was.

Q. Do you recall that he was one of the first medical directors for the Ethicon products from approximately 1999 to 2000 or 2001?

A. That sounds about right.

Q. And do you remember him testifying that he considered himself the chief safety officer for the TVT product?

A. Yes, I think that was his opinion.

Q. Okay. Do you have any opinions as to whether or not that's true, that Dr. Isenberg, as the medical director for the TVT products, was the chief safety officer for the TVT?

A. I have no opinion on that.

Q. If he was the chief safety officer for the TVT, does that change your assessment of the reliability of the information that he offers?

A. It does not. I don't know exactly what a chief safety officer entails.

Q. You would agree with me that the medical literature is relevant information that you would want to consider prior to issuing your opinions in this case; right?

A. Say that again?

Page 38

me that that's relevant information that you would want to know prior to issuing your opinions, is the differences between the four products that you are offering opinions on; right?

MR. KOOPMANN: Object to the form.

THE WITNESS: So in regards to the four products, they are all -- there are very, very subtle differences between them. The relevant differences are actually minimal, but there are some very subtle differences, and I do believe I am aware of most of them.

BY MR. FAES:

Q. Okay. And my question was, simply, that's information that you would want to know and consider before issuing your opinions; right?

A. As long as it's relevant, yes.

Q. Okay. Would you agree with me that each of the products that you are offering an opinion on in this case, the TVT, the TVT-O, the Abbrevo, and the Exact have different safety profiles?

A. They have different safety profiles, yes, there are.

Q. Okay. Do you think it was important, before offering your opinions in this case, to understand the differences between the four products that you are

Page 39

offering an opinion on and other polypropylene mid-urethral slings?

A. Again, in regards to -- going back to your previous question as well, in regards to safety profiles, there's such overlap and redundancy between all of these products that the way that they are used, their intent for use, the actual materials, that the safety profiles are really very, very similar between all of them. If there are subtle differences between one versus another, the actual relevance of these safety profiles is not significant. That was the previous question. What was the most recent question?

Q. My question was, do you agree that it's important to understand the differences between the four products that you are offering an opinion on in this case and other polypropylene mid-urethral slings?

A. These four products and other mid-urethral slings, again, they are all -- the subtle differences between them, although there are subtle differences, I don't believe that they are very significant. I believe that there's -- the differences between all of them are minimal and not really clinically relevant.

Q. But you would agree with me that -- well, strike that.

Would you agree with me that it was important

Page 40

for you to know those differences prior to issuing your opinions in this case, or do you disagree with that?

A. I don't think that the differences factor into my opinion, so I don't think that they are relevant, despite being subtle differences between all these products. The actual safety and actual intent of use, actually how they are used, they are all pretty much the same. And even in regards to TVTs and other non-TVT mid-urethral slings.

Q. And for a number of opinions in your report, you actually are discussing the safety and efficacy profile of mid-urethral slings in general, not specifically the TVT; right?

A. Most of it is general, and I do believe that the safety profiles of the TVT does translate to almost all mid-urethral slings.

Q. Okay. Would you agree with me that the four TVT devices that you are offering -- well, strike that.

Would you agree with me that, for instance, the TVT retropubic device has a different safety profile than, say, the --

A. I --

MR. KOOPMANN: Wait.

Page 41

MR. FAES: Strike that. Let me restart.

THE WITNESS: Okay. Sorry.

BY MR. FAES:

Q. Would you agree with me that the TVT retropubic device, the TVT Classic, has a different safety profile than, say, the AMS SPARC?

A. Yes.

Q. Would you agree with me that the TVT retropubic has a different safety profile than the Boston Scientific Advantage?

A. On certain components, yes. On the basic structure in regards to placement, on how they are placed and where they are placed, it's the principles, I believe, are the same for all of these.

However, there might be subtle differences in regards to whether you are taking the transobturator route or the retropubic route, but the sling itself is the same for all of them.

How it's placed and where it's placed, yeah, there are a couple of differences there and things you have to watch out for when you are actually placing them. However, the actual sling itself is the same for all.

Q. So you would agree with me that the four TVT products that you are offering an opinion on have a

Page 42

different safety profile than other full-length polypropylene mid-urethral slings; right?
A. Say that again.
Q. You would agree with me that the four TVT products that you are offering an opinion on in this case have different safety profiles than some of the other full-length polypropylene mid-urethral slings that are still on the market; right?
A. I do not. I think that they are pretty much all the same. I think that all mid-urethral slings, the safety in regards to these products are -- and we're talking about the TVT, the macroporous, all of those, that they are all pretty much the same.
In regards to the subtle differences, like with the SPARC and when you asked me earlier with regards to the SPARC and the traditional classic TVT, it's just how it's placed, and that's more of a technical issue of the placement itself than how you are doing it, the mechanics of doing it. It's not at all for the actual sling itself. The safety profile for the actual sling is similar throughout.
Q. Okay. So when you issued your opinions in this case, is it fair to say that you didn't do a comparison of the safety profile between the -- say, the TVT and the TVT-Exact sling versus the other

Page 43

retropubic slings that are available?
A. I have looked at literature that does compare different companies' products as well.
Q. Okay. And did you -- what was -- how did you conclude, upon looking at that data, that there was no difference in the safety profile between the TVT and TVT-Exact versus the other --
A. Companies? Sorry.
Q. -- retropubic slings?
A. They are all -- based upon the literature, they are all kind of the same in regards to risks of the sling itself.
In regards to placement of the sling, in regards to where it goes and what structures are involved and the dissection involved and which direction you choose to place the sling, that is different between them. However, the actual sling itself, they are the same.
Q. Okay. So you said a minute ago all retropubic slings are kind of the same. Are you saying they are kind of the same or they are all the same?
A. Sorry. All the slings are the same, yes.
Q. For retropubic?
A. For all -- macroporous polypropylene slings

Page 44

pretty much -- they are the same. The actual sling itself is the same. How you implant that sling, how you -- where you place that sling, there are subtle differences.
Q. Okay. And just to be clear, my question is specific to the safety profile. You are saying that the safety profile is the same of all the polypropylene full-length mid-urethral slings?
A. Yes.
Q. Is your answer the same if we're comparing the retropubic slings to, say, mini-slings such as the TVT-Secur, Altis RS?
A. Yes, I believe the safety profile is the same in regards to the sling itself, as opposed to the mini-sling, which I was not offering an opinion on here today. The mini-sling, it's the same material. So I do think that the sling itself is equally as safe as the retropubic.
As far as placement goes, as far as location, as far as how it's placed and the actual placement itself, there are differences between that.
Q. And your answer is the same even with regard to slings that are no longer on the market, such as the Bard Align or the AMS SPARC; right?
A. I'm not familiar with the Bard Align. I

Page 45

don't know that one. The other ones, the macroporous, large-pore polypropylene, their safety profile is the same for all of these mid-urethral slings.
Q. Even if they are no longer being sold; correct?
A. The fact that they are being sold or not being sold is -- doesn't factor in.
Q. And you have an understanding that some of the retropubic slings are no longer on the market -- right? -- such as the AMS SPARC?
A. The AMS, MonArc, and SPARC, yes.
Q. And you have an understanding that the Bard Align and the Bard Align TO are no longer on the market. I think you said you weren't too familiar --
A. I'm not too familiar -- sorry. I'm not very familiar with the Bard product. However, the AMS products, I am aware that they are no longer on the market.
My understanding is that it has to do with marketing or business stuff from AMS, but I don't really know too much about that.
Q. And where do you have that understanding from?
A. You know, I'm just kind of guessing, I guess. I'm just kind of guessing. I'm not 100 percent sure.

Page 46

MR. KOOPMANN: Don't do that.
THE WITNESS: Okay. Sorry.
BY MR. FAES:
Q. So it's fair to say that -- strike that.
Would the answer to my question be the same if I'm asking if you've done a comparison between -- in terms of the safety profile between the TVT-O and Abbrevo versus other obturator slings that are still on the market such as the Boston Scientific Lynx or any other obturator slings on the market?
A. I feel that they are equivalent in safety.
Q. Okay. So is it fair to say that, because you are offering an opinion in this case that the four TVT products that you are offering an opinion on, TVT, TVT-Exact, TVT-O, and TVT-Abbrevo, are all safe and effective and they have the same safety profile as other full-length mid-urethral slings; is it your testimony that all full-length mid-urethral slings are safe and effective?
A. So as far as all ones, I am not saying all. I don't know what you mean by "all." But I do know that, the ones I am familiar with, they are equally as safe in regards to the sling itself.
In regards to placement of the sling, again, there are subtle differences and there are different

Page 47

things you need to watch out or look for on the different locations and placement and how they are placed in regards to the procedure itself.
But they are all -- the macroporous mid-urethral slings, as far as my knowledge goes and my familiarity with the products that are out there, I don't know if there's other products out there that I'm not aware of, so that's why I can't say all.
Q. Well, so it's fair to say that if all mid-urethral slings have the same safety profile as the four TVT products you are offering an opinion on, and the four TVT products you are offering an opinion on are all safe and effective, then all mid-urethral slings must be safe and effective; right?
A. I would have to review specific -- I did a lot of work on these four specific ones, so I reviewed a lot of information on those. So my opinion today is based on these, but if I were to do a review of those others, I would have to come to that opinion after reviewing all of the literature on those.
So my opinion today is just on these four products. So to place my opinion on other products that are not included in this review would be a little presumptuous, but I do think that mid-urethral slings made out of macroporous mesh generally are, but I

Page 48

would have to review all the literature in order to address one specific sling that you are referring to.
Q. In doing your -- well, strike that.
I think you state in your report, if I can find it -- Doctor, in your report on page 2 you state you choose to use Ethicon's TVT, TVT-Exact, TVT-O, and TVT-Abbrevo devices "to treat my patients' stress urinary incontinence"; right?
A. Page what?
Q. Page 2.
MR. KOOPMANN: I'll object to the form just to the extent I think you said "choose" and it says "chose."
MR. FAES: Oh, strike that. Good catch there, Barry. Thanks.
Q. So your report here says that you chose to use Ethicon's TVT, TVT-Exact, TVT-O, and TVT-Abbrevo devices to treat your patients' stress urinary incontinence; right?
A. Yes.
Q. Do you choose --
Thank you, Barry.
Do you still choose to use all four of those devices in your practice currently?
A. Currently I'm not using these products.

Page 49

Q. Okay. Why not?
A. Because when I moved here -- I've been here in Las Vegas practicing here for about three years now, and the contracts from the hospitals were directed toward different products. So the hospitals have now got a better deal from a different product, and that's the only reason why I'm not using any of these products. Were they available at my hospitals that I work out of, I would absolutely use them.
MR. FAES: Well, thank you, Barry. I would have just blown right past that if you hadn't pointed that out.
Q. So what products are you currently using in your practice to treat stress urinary incontinence?
A. Currently the hospitals have contracts with a retropubic mid-urethral sling company and transobturator mid-urethral sling company named Caldera.
Q. So right now, currently, you are exclusively using Caldera products to treat SUI; is that accurate?
A. That is accurate. That's what the hospitals have the best contract with.
Q. Okay. And specifically what products do they have for the retropubic and the obturator approach?
A. They have, it's a mid-urethral sling, the

Page 94

still use it, but I do think that mid-urethral slings are a far better route to go for stress urinary incontinence.

Q. But if a physician were to perform the Burch procedure for the treatment of stress urinary incontinence today, would you agree with me that that would still be within the standard of care?

A. I think that the standard of care is a mid-urethral sling. I think that the standard of care is a mid-urethral sling. Is a Burch procedure an option for certain surgeons? Sure. That's up to them.

But in regards -- in my practice and in regards to my understanding of how most physicians and surgeons that take care of urinary incontinence, I would say that mine and my colleagues' standard of care is a mid-urethral sling.

Q. Would you agree with me that if a physician chose to use the Burch procedure for the treatment of stress urinary incontinence today, that would not be below the standard of care?

A. Well, you know, I don't know, on that. I don't want to, like, argue with a different surgeon, but I do think that they are choosing a procedure that has more morbidity and less efficacy, so I would kind

Page 95

of wonder why they would choose a procedure that didn't work as well and that has more morbidity. So I do think it's probably below the standard of care. I don't think standard of care is kind of like this written-in-stone thing.

I think that most contemporary active surgeons that take care of stress urinary incontinence would use a mid-urethral sling. I think that if you use a Burch procedure as your primary procedure for stress incontinence, you are an outlier, it's an outlier. I would say it would lie outside the standard of care.

Q. So it would be your opinion that a surgeon that uses the Burch procedure for their primary procedure currently is not a contemporary active physician?

A. No. I think there are a lot of contemporary active physicians that do use Burch procedures, but I think that those physicians would be considered an outlier in regards to how to address stress incontinence. I think in their hands they think that is the best for their patients, but I think that the bulk of surgeons that take care of stress incontinence will choose a mid-urethral sling for their patient -- for most of their patients.

Page 96

Q. Well, do you believe that being an outlier or someone who doesn't go with conventional wisdom with regard to a surgical procedure is falling below the standard of care?

A. You keep referring to the standard of care as this rock-defined thing, and I don't really have a black-and-white definition of standard of care. I don't really know if there's a black-and-white definition of -- however, I would think that in -- if I were talking to a colleague and they said that they still did a Burch procedure as their primary procedure, I would think that they are not choosing the optimal -- not choosing the best procedure for stress urinary incontinence due to the efficacy and complications.

Q. So if I understand you correctly, you are saying that you don't have a black-and-white definition of the standard of care. Is that accurate?

A. No. I mean, I do think that the mid-urethral sling is the -- the reason why I'm kind of dancing around this is I hate to criticize other physicians and other surgeons in their choice on what to do for their patients, and I hate providing commentary for -- if it's a colleague or somebody, if that's what they think is best.

Page 97

But it's my opinion that the standard of care today for stress urinary incontinence is a mid-urethral sling, and I would say that the surgeon that chooses a Burch procedure for a mid-urethral sling is kind of -- is performing outside the standard of care.

Q. So it's -- is it your opinion that a physician that chooses a Burch procedure over a mid-urethral sling is essentially committing malpractice?

A. No, absolutely not.

Q. Would you agree with me that using a --

A. I don't think that it is malpractice, but I do think that it's an option that they can pursue for their patients, but I think that there are better choices.

Q. Do you believe that the Burch procedure is a reasonable treatment option for a patient who does not want mesh for the treatment of their stress urinary incontinence?

A. Yes.

Q. If a patient came to you and after going through the various options and informed consent with you, they told you that they didn't want to have a mesh sling for the treatment of their stress urinary

Page 98

incontinence, what other options would you present to them at that point?
A. I would be hard-pressed to perform a Burch procedure now, and the reason why is because I would tell them, I would say, look, there's a better procedure out there that holds less morbidity, that works better than a Burch procedure.
So in my practice and with my patient in front of me, I would say I wouldn't want to do a Burch procedure on you simply because it's -- I have a better option, and I wouldn't want to do a procedure on a patient that I think is going to have a higher risk with a lower efficacy. And if there are concerns about the mesh, I would try to address those concerns specifically.
Q. If a patient ultimately decided that they wanted to proceed with a non-mesh surgery for their stress urinary incontinence, whether it be a Burch procedure or an autologous fascial sling, would you refer that patient to another doctor in order to perform those procedures?
A. I wouldn't refer, but I would try to convince them that there's better procedures out there and I don't feel comfortable performing a procedure on somebody that has better options.

Page 99

Q. When you --
A. If they choose to pursue treatments elsewhere, I guess that's up to them.
Q. When you present surgical treatment options for the management of a patient's stress urinary incontinence during your informed consent discussions, is the polypropylene sling the only surgical option that you present to your patients?
A. I present them the best option out there, and that is the best option. So do I present them with alternative options? No, typically I do not, and the reason why is because I do think that this is the best option for patients.
I mean, they used to do MMKs in the past too for -- and I don't think Marshall, Marchetti and Krantz are doing MMKs either, because there are better options out there.
Q. So if after having an informed consent discussion about the risks and benefits of mesh surgery, a patient said no, thank you, Doctor, I would like a different option than mesh to treat my stress urinary incontinence, would you tell them about other surgical mesh procedures or would you just say, well, that's the only option I have?
A. No. I would tell them, I would say, look,

Page 100

the mesh procedure is the best, least morbid, most effective procedure out there. There are other options. There are other alternative procedures for stress incontinence. However, they are inferior procedures, and I don't feel comfortable performing an inferior procedure on you to address something.
Q. If a patient asked what those inferior procedures are, would you describe those, what you believed --
A. Sure.
Q. -- are inferior procedures to them?
A. Yes, I would.
Q. And what are the other alternative procedures that you would describe?
A. The ones we just talked about. There's a Burch procedure, autologous sling. I wouldn't bring up an MMK. Those procedures are really not good.
Q. Okay. And if upon hearing those alternative options of a native tissue sling or a Burch procedure, a patient was interested in those options and wanted to explore them further, what would you do at that point, other than try to convince them that the sling is a better option?
A. You know, I'd have to be in the situation and really talk with the patient to get a sense of

Page 101

understanding. So honestly, I don't know what I would do.
Q. But ultimately, if a patient came to you and said, Look, Doctor, I've researched the options on my own, and I want either a Burch or a native tissue sling, you would essentially at this point refuse to do either of those procedures on your patients?
A. I would do my best to convince them that there are other procedures out there that are superior. Would I do that? It depends on the patient. It depends on what's going on. It depends on the larger clinical picture. But it is something that is available but I don't think is the optimal choice.
Q. Do you feel like you could still do a -- competently do a Burch procedure or a native tissue sling despite not having done one since 2006?
A. Burch procedure I could do. Burch procedure I could do. Yeah, I could do both of those, yes. They are both -- technically they are not that challenging of a procedure, so yes, I could do both.
Q. So if a patient ultimately insisted on one of those procedures, would you attempt to do those procedures yourself, or would you feel more comfortable referring that patient to a physician that

Page 230

mesh is the cause of the dyspareunia? I do not.
Q. Would you agree that a woman can experience scar plate formation from a mesh implanted in the vagina?
A. I don't think that scar plate formation really exists. I don't really buy into that.
Q. Would you agree that a woman can experience scarring from mesh following implantation?
A. Yes, with all surgeries there's scarring associated with it.
Q. Would you agree with me that women can experience chronic or long-term dyspareunia from that scarring?
A. With any surgery there can be some pain associated with intercourse. Whether or not you are using a mesh or -- or you are using mesh, there's higher dyspareunia rates associated with Burch procedures, higher dyspareunia rates associated with pubovaginal slings.
So I don't think that's something unique to the mesh procedure. I think it's something inherent in all procedures in the vaginal area.
Q. But you would agree with me that a woman can experience chronic or long-term dyspareunia from scarring that comes from the mesh; right?

Page 231

MR. KOOPMANN: Object to form.
THE WITNESS: No. I think that it's scarring from surgery, not necessarily from the mesh, because when you look at these dyspareunia rates and you look at the other procedures that have been used in the past in regards to dyspareunia, mid-urethral slings actually have the lowest dyspareunia rate when you start comparing things out. So I think it's inherent of surgery, not at all the mesh.
BY MR. FAES:
Q. Would you agree with me that frayed edges of a mesh can injure a woman's vagina?
A. I don't think that the frayed edges are a factor.
Q. So you believe that if a TVT or other mesh becomes frayed, that that fraying can't injure a woman's vagina?
MR. KOOPMANN: Object to form.
THE WITNESS: Do I think fraying can -- so in regards to frayed edges, I think -- you know, I think that the mesh can have an exposure. I think you can have poor healing. I don't necessarily think that it's the frayed edge itself. I mean, exposures do happen, and I wouldn't necessarily point the finger at a frayed edge.

Page 232

I would say it's more a part of the healing process. Any time you implant something, if it doesn't heal properly, it may result in a low percentage -- it can result in an exposure. But just like a Burch procedure, you can get an exposure too. With an allograft or a xenograft you can get exposures too.
So in regards to the frayed edge specifically, I think it's anything that's implanted can have an exposure.
BY MR. FAES:
Q. So you would agree with me -- well, strike that.
First of all, do you believe that a TVT mesh edge can become frayed?
A. If you pull on a TVT too hard, in nonphysiologic conditions it can become a little stretched out.
Q. So is it your opinion that the only way that a TVT mesh edge can become frayed is if you pull it too much?
A. In clinical practice, the way that the sling was actually intended to be used, you should not have edges that are frayed, because there's no excessive force on the device. It should scar in nicely.

Page 233

Q. So you would agree with me that if you took, for example, a TVT or TVT-O mechanically-cut mesh out of the box and the edges were frayed before you implanted it in the patient, then you wouldn't use that device in a patient and you would get another one?
A. What do you mean by "frayed"?
Q. I mean, that there's frayed rough edges of the mesh that are visible prior to implanting it in the patient.
MR. KOOPMANN: Object to form.
THE WITNESS: I mean, that hasn't happened. The edges of the mechanically-cut mesh are -- they are pretty straight across, and I don't think that when placed properly, I don't -- I haven't found them to be frayed. I think we're talking about two different things.
I think that the fraying that I'm referring to is if you put an excessive amount of force on -- a nonclinical excessive force on the sling, it can stretch out and become unravelled a little bit, but the ones that come out of the box that are mechanically cut are fine.
BY MR. FAES:
Q. You state in your expert report that you have

Page 234

seen no evidence in your practice or the published literature indicating that particle loss occurs in the body.

You have never reviewed or read any documents from Ethicon indicating that particles can migrate through the vaginal tissue and cause pain?

A. You know, I've seen some internal documents that referenced that, but that's not what I feel to be the case.

Q. Have you ever encountered a sealed blister or sealed box of TVT or TVT-O that had loose particles floating around in the package before you used it?

A. I don't think I have. Honestly, I haven't really looked, but I don't recall seeing anything like that.

Q. If you were to encounter that, would you still go ahead and use the device, or would you consider that fine, that there's particles floating around in the box that aren't attached to the mesh?

A. Again, this is kind of a hypothetical type of a situation that you are throwing out there, so I don't know. I don't know.

Q. Okay. So you say it's a hypothetical. You've never actually seen internal documents from Ethicon and Johnson & Johnson where sealed blister

Page 235

packs of TVT-O were returned to Ethicon and Johnson & Johnson for precisely that reason, because there were particles, items floating around in the package?

A. I may have glanced over one of that in the review materials that have been provided, but you know, I didn't really pay too much attention to it.

Q. If you were to encounter that situation in your clinical practice today, would you consider that to be a defect or problem with the mesh, or would you just go ahead and use it in your patient and figure it's fine?

MR. KOOPMANN: Object to form.

THE WITNESS: Again, if there's little particles floating around there, would I use it? If the mesh looked okay and if it was intact, yeah, sure.

BY MR. FAES:

Q. Okay. While you state that you have seen no evidence in your practice or published literature indicating that particle loss occurs in the body, would you agree with me that if particle loss is occurring in the package, in the blister package before you even place it in a patient, that that's evidence that the mesh is at least physically degrading?

Page 236

MR. KOOPMANN: Object to form.

THE WITNESS: No.

BY MR. FAES:

Q. So you don't consider particle loss in a blister package to be evidence of physical degradation of the mesh?

A. I do not, but again, you are throwing out these hypotheticals at me, and I'm going -- you know, I'm kind of making it up as I go, honestly.

Q. Okay. Well, I mean, they are not hypothetical because they have actually occurred.

A. And I'm kind of guessing about these things and I'm going -- and honestly, I don't really know, but I wouldn't think that anything is degrading.

Q. Okay. What would you need to see in order for you to think that a TVT mesh was physically degrading?

A. What would I need to see in order to think that it's degrading?

Q. I mean, if particles falling off the mesh isn't evidence of degradation to you, what is?

A. I haven't really thought about that. What would I need? Well, so now I'm trying to address a hypothetical with another hypothetical. So if I took the mesh out of the box and I touched the mesh and I

Page 237

crinkled it up and it dissipated, I think that possibly would degrade, but that doesn't happen. I'm just making stuff up.

Q. So hypothetically --

A. I've got an idea. If I got a box and it was packed with a mesh and then I opened it up and the handles were just there and there was no mesh there, that would be degraded. You know, I'm answering these what I think is kind of an off hypothetical question with off hypothetical answers, and I'm sorry I'm doing that but it's...

Q. So hypothetically, if you picked up the mesh and it completely fell apart in your hands, it would be evidence to you of physical degradation; right?

A. It's a goofy answer because I think it's kind of a goofy question. No offense. I'm sorry. But I'm just kind of making stuff up, and I'm sorry about that.

Q. But just to be clear, just particles falling off of the mesh wouldn't be physical evidence to you of physical degradation?

A. If there were a couple of fibers, no, it would not.

Q. Okay. Do you know whether or not Ethicon actually has design and manufacturing specifications

Page 246

not popping up in my head right now.
Q. Are you aware that the TVT mesh tested moderately or markedly cytotoxic on four separate occasions prior to the TVT being launched in the United States?
A. So in regards to previous studies on cytotoxicity, the body of knowledge, the evidence right now in regards to use of a mid-urethral sling is that it is not cytotoxic.
The previous studies that were done in the past, I'm sure there's lots of studies that looked at -- I'm elaborating too much. I feel that the body of knowledge in regards to cytotoxicity and the TVT is that it's not cytotoxic.
When you look at this and you say, okay, 99.8 percent or 99.2 percent of the patients do not have an erosion or, you know, very, very low percentage of patients have an erosion, it says to me, hey, it's not cytotoxic.
The erosion I do not feel is a result of cytotoxicity. An erosion has to do with healing, has to do with other issues other than -- not cytotoxicity.
Q. Well, you would agree with me that if the mesh material were cytotoxic, that an erosion could

Page 247

be -- strike that.
You would agree with me that if a mesh material were implanted that were cytotoxic, a mesh exposure could be a potential result of exposure to that cytotoxic substance; right?
A. I would be guessing. I don't know the answer to that. That's a hypothetical that I have no idea. I'm just guessing.
Q. Okay.
A. And earlier I was talking about if you placed a cytotoxic substance next to the mesh, it would cause necrosis. Again, on that one I'm guessing too. No one would place chemotherapy agents intentionally to see if it necrosed vaginal tissue. It's just not done. These are kind of hypothetical situations that I'm kind of making up to say, you know, well, maybe, but the reality is that this is not cytotoxic, this is not what's causing necrosis, this is not causing these erosions.
Q. As an expert for Ethicon and Johnson & Johnson who is giving the opinion that the mesh is not cytotoxic, how do you explain the four separate tests that Ethicon and Johnson & Johnson did that showed that the TVT mesh was markedly or moderately cytotoxic?

Page 248

A. Which ones are you talking about?
Q. First of all, are you aware --
A. Yes.
Q. -- that there have been four separate tests?
A. Yes. In the '90s, I don't really place too much value on those based upon the current body of evidence, which says that it is not cytotoxic.
Q. Are you aware of any cytotoxicity testing that Ethicon and Johnson & Johnson have done after the launch of the TVT mesh in the United States, specifically with regard to cytotoxicity?
A. I'm sure I've read a couple of those as well.
Q. You believe you have seen cytotoxicity tests done on the TVT mesh after 1998?
A. I'm trying to think.
Q. I'd sure like to see them if they are out there.
A. You know, it's not jumping out right this second. Everything is kind of meshing in my head.
Q. I'm talking specifically about cytotoxicity.
A. I understand. Everything is kind of getting mixed up in my head as we're speaking --
Q. And you understand, from your review of the records, that one of the industry standard ways to check for cytotoxicity that's required is an ISO

Page 249

elution test; right?
A. I mean, I think that was in one of the articles, yes.
Q. Okay. And are you aware of any instance where Ethicon and Johnson & Johnson shared the results of its positive cytotoxicity tests with the TVT mesh with the FDA?
A. You know, again, those studies are kind of jumping away from me right now. I can look them up, but...
Q. Well, let me ask you this:
Do you believe that those results should have been shared or disclosed with the FDA?
MR. KOOPMANN: Object to form. Foundation.
THE WITNESS: As of right now I'm kind of getting flustered in regards to what I read and those specific studies.
BY MR. FAES:
Q. Do you believe that the results of the cytotoxicity testing where the mesh tested cytotoxic on four separate occasions should be shared or disclosed to doctors who might choose to use the device?
A. Well, I kind of focus on the bulk of the data, and the bulk of the data, the bulk of the

Page 250

level I data. And as a clinician, cytotoxicity doesn't happen. It is not an issue in regards to how we use this mesh, in regards to how it's implanted, and in regards to healing.

The mesh itself is actually really well tolerated in its appropriate use, and I don't feel as though it is cytotoxic. I think that most of the time, with a very, very low erosion rate, a very low exposure rate, that it isn't cytotoxic.

When you think about it, if a product is cytotoxic, and 99 percent of the time there's no erosion, there is no reaction, it's inert. And to say that something is cytotoxic, I would expect 99 percent of the time for there to be something going on, and there isn't.

Q. So, well, you would agree with me that it's not -- the TVT mesh isn't well tolerated in the 2 to 3 percent of people that have an erosion or exposure; right?

A. No, I don't say that either. I'm not saying that that's cytotoxicity. I don't think that it's cytotoxicity that's causing the erosion. I think that is scarring and healing that is causing the erosion. I think that it's just sometimes it doesn't heal as well as you would like. I don't think that's a

Page 251

function of the mesh. I think that's a function of all implantable devices, and anything you implant can have an erosion, can have an exposure. I don't think that it's cytotoxicity from the mesh that's contributing to -- when you -- like I said, again, when you look at the body of knowledge, how well it is tolerated, you kind of come to the conclusion that it's inert.

Q. What type of frequency and complications would you need to see from a mesh before you would start to consider that the material may be cytotoxic?

A. You know, that's a hypothetical question again. I don't have a pre-set number of what I would say or not say. All I know is that the exposure rate for the TVT is low, it's very low. It's inert. It is well tolerated in the body. It does not cause cytotoxicity. When you look at complications from alternative procedures, things like pubovaginal slings and Burch procedures, there's way more complications with those.

Q. So you would agree with me that you can't articulate any objective standard for the type and frequency of complications that you would need to see from a mesh before you would start to consider that it's cytotoxic; right?

Page 252

MR. KOOPMANN: Object to form.

Go ahead.

THE WITNESS: In regards to -- again, it's a hypothetical situation that I'm kind of like scratching my head about, because I don't think this is a cytotoxic agent.

So if you are saying, okay, this noncytotoxic agents, how many erosions, what percentage of erosions would you have to see in order to say it's cytotoxic. You know, I don't know, because I have no idea what a cytotoxic substance would do in the vagina, because this isn't cytotoxic.

BY MR. FAES:

Q. So what objective standard are you applying for your opinion that the TVT mesh is not cytotoxic?

A. I'm applying the medical societies, I'm applying the literature that's out there that repeatedly over and over says there's no cytotoxicity, that this is well tolerated in the vagina, that it's compatible with its intended use.

Q. So what would you need to see in order for you to reconsider your position that the mesh is cytotoxic?

A. I don't know. I don't have an answer to that question because it's what I would think is an obscure

Page 253

hypothetical situation.

Q. You stated that you believe that the erosion rate for the TVT products is low. Is that accurate?

A. That is correct.

Q. Do you have an opinion that you intend to offer in this case as to what you believe the erosion rate is for the TVT retropubic?

A. I think I quoted right around under 2 percent.

Q. So you believe it's under 2 percent?

A. Yes.

Q. Is your answer the same with regard to the TVT-O?

A. Yes.

Q. The same with regard to the Abbrevo?

A. Yes.

Q. Same with regard to the Exact?

A. Yes.

Q. Would you agree with me that your opinion that the erosion rate is low and is less than 2 percent is part of the reason for your conclusion that the TVT devices are safe?

A. That is one specific complication regarding the TVT, and I think that is a low, easily fixable, low-severity complication. When you talk about

Q. And the Schimpf study, that is also a meta-analysis and not a randomized controlled trial with a primary endpoint of safety; right?

A. Correct. And again, I place high value on meta-analyses.

MR. FAES: That's all the further questions I have.

MR. KOOPMANN: I'd like to have the witness read and sign.

And just for the record, just so we're clear, USB drive, Deposition Exhibit 9, you want to retain that, Andy?

MR. FAES: Yes. Unless you want me to send it to her for some reason. I'm just going to put it on the Cloud and it's going to sit in my desk drawer with 500 other drives that I've gotten from defense lawyers over the past five years.

MR. KOOPMANN: I think you should save this so we have some record.

MR. FAES: Yeah. It will be in the drawer along with all the other ones, and also be in the Cloud, because we all live forever on the cloud.

MR. KOOPMANN: You might want to write "Wasserman" or something on there.

MR. FAES: That's a good idea.

MR. KOOPMANN: There is a password for it that I'll tell you off the record.

MR. FAES: Okay.

(End of proceedings at 5:29 p.m.)

* * * * *

DECLARATION OF DEPONENT

PAGE LINE CHANGE REASON

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

I, RICHARD M. WASSERMAN, M.D., deponent herein, do hereby certify and declare under penalty of perjury the within and foregoing transcription to be my deposition in said action; that I have read, corrected and do hereby affix my signature to said deposition.

_____

RICHARD M. WASSERMAN, Deponent

Date:_____

I, the undersigned, a Certified Shorthand Reporter of the States of Nevada and California, Registered Professional Reporter, and Certified Realtime Reporter, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were duly sworn; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that before completion of the proceedings, review of the transcript was requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: 08-19-2019

_____

JANET C. TRIMMER, RPR, CRR

NV CCR No. 864, CA CSR 4008